

# EXHIBIT D

Konstantin Walmsley, M.D.

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON

- - -

IN RE: ETHICON, INC., : MASTER FILE NO.  
PELVIC REPAIR SYSTEM : 2:12-MD-02327  
PRODUCTS LIABILITY : MDL 2327  
LITIGATION :  
: JOSEPH R. GOODWIN  
: U.S. DISTRICT JUDGE

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SHERRY FOX and ROY FOX, JR. :  
Plaintiffs, :

v. :

JOHNSON & JOHNSON, INC. and :  
ETHICON, INC., :  
Defendants. :

- - -

March 23, 2016

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Oral deposition of KONSTANTIN  
WALMSLEY, MD taken pursuant to notice, was held at  
the law offices of Mountainside Hospital, 1 Bay  
Avenue, Montclair, New Jersey, beginning at 12:23  
p.m., on the above date, before Ann Marie Mitchell,  
a Federally Approved Certified Realtime Reporter,  
Registered Diplomate Reporter and Notary Public.

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GOLKOW TECHNOLOGIES, INC.  
877.370.3377 ph | 917.591.5672 fax  
deps@golkow.com

1 APPEARANCES:

2

3

TRACEY & FOX

BY: CLINTON J. CASPERSON, ESQUIRE

4

440 Louisiana Street

Suite 1901

5

Houston, Texas 77002

(713) 925-7216

6

ccasperson@traceylawfirm.com

Representing the Plaintiffs

7

8

ROERIG, OLIVEIRA & FISHER, LLP

9

BY: DAVID G. OLIVEIRA, ESQUIRE

10225 North Tenth Street

10

McAllen, Texas 78502

(956) 393-6300

11

doliveira@rofllp.com

Representing the Defendants

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1 Q. It goes on to say, mesh-related  
2 complications can occur following polypropylene  
3 sling replacement, but the rate of complications is  
4 acceptably low.

5 Do you agree with that statement?

6 MR. CASPERSON: Objection, form.

7 THE WITNESS: I think from a  
8 quantitative statement, that's a true comment.

9 MR. OLIVEIRA: Doctor, if you don't  
10 mind, let's take a little break, and we'll move into  
11 phase 2.

12 THE WITNESS: Thank you.

13 - - -

14 (A recess was taken from 1:04 p.m. to  
15 1:21 p.m.)

16 - - -

17 BY MR. OLIVEIRA:

18 Q. If you could I'd ask you to turn to  
19 your report, which we have marked as -- I believe as  
20 Exhibit 2 in this case.

21 A. Yep.

22 Q. It looks like the first four or five  
23 pages of your report are kind of background  
24 information and mentions, I guess, the medical  
25 records and depositions that you reviewed, along

1 with the medical literature and other documents that  
2 you reviewed. Correct?

3 A. Yes.

4 Q. And then you do -- at some point you  
5 have a clinical history where you -- it looks like a  
6 little chronology where you list a number of  
7 different things in her medical history, I guess,  
8 that you believe were significant?

9 A. Yes, sir.

10 Q. Then after that, you get into what  
11 looks like the couple of general opinions?

12 A. Yes, sir.

13 Q. And then five case-specific opinions  
14 or -- yes, it looks like it's five. Is that  
15 correct?

16 A. Yes.

17 Q. So let me ask you about your first  
18 opinion.

19 Your first general opinion, you state  
20 there at the bottom that it's your opinion "the IFU  
21 for the TVT in 2002 was not sufficient to enable  
22 informed consent from the patient."

23 What do you base that on?

24 A. I base that on my clinical experience  
25 with TVT and, for that matter, other polypropylene

1 mesh slings and the IFU that I reviewed that dated  
2 back to the time when this sling was implanted.

3 Q. And what do you believe is missing  
4 from this IFU that you would put in it?

5 A. Well, there are a lot of potential  
6 complications that were not mentioned in the IFU  
7 that I've listed in my report.

8 Q. Doctor, would you agree with me that  
9 generally, that IFUs typically don't include every  
10 potential adverse reaction or complication? Isn't  
11 that correct?

12 A. Not necessarily.

13 Q. So you believe that they should have  
14 every adverse reaction or every possible reaction to  
15 the product?

16 A. I think they should have the majority  
17 of them, the ones that are the most likely to occur.

18 For those that are case-report like  
19 complications or case-report like findings, I would  
20 agree with you, those don't necessarily need to be  
21 in the IFU. But certainly the ones that you see  
22 with even some regularity or occasional regularity  
23 should be mentioned.

24 Q. So tell me, then, which ones do you  
25 believe should be in there?

1           A.       Well, first, as far as complications  
2   to be mentioned, mesh contraction would be one.  
3   Dyspareunia. Mesh shrinkage. Scar plate formation.  
4   The difficulty in removing mesh.

5           Q.       Are those all the ones you feel  
6   should be in there?

7           A.       That's the majority of them, yes.

8           Q.       You would agree with me that a doctor  
9   not only has to rely on the IFU for explaining, I  
10   guess, the adverse reactions and possible side  
11   effects to a plaintiff.

12                    Would you agree with that?

13          A.       I'm sorry. Could you repeat that  
14   question?

15          Q.       Well, can doctors also rely, don't  
16   they also rely on their experience, their clinical  
17   experience in implanting mesh or in this particular  
18   case, to rely on -- in providing an informed consent  
19   to the plaintiff?

20          A.       I think that's a true comment, yes.

21          Q.       And do you do that in your practice?

22          A.       I do.

23          Q.       And do you include things when you go  
24   over your informed consent that are not necessarily  
25   included in the IFU?

Konstantin Walmsley, M.D.

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CERTIFICATE

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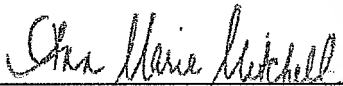
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I HEREBY CERTIFY that the witness was  
duly sworn by me and that the deposition is a true  
record of the testimony given by the witness.

It was requested before completion of  
the deposition that the witness, KONSTANTIN  
WALMSLEY, MD, have the opportunity to read and sign  
the deposition transcript.

ANN MARIE MITCHELL, a Federally Approved  
Certified Realtime Reporter, Registered  
Diplomate Reporter and Notary Public

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